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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,089	12/01/2003	Jamieson Crawford	3896-031546 (P-6061)	1755

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/725,089	CRAWFORD, JAMIESON	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/1/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 24* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,7-10,12,15-17,20-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuracina et al. (6,443,929).

Kuracina et al. discloses a safety needle assembly that includes all of the limitations as recited in claim 1. See Figures 23 and 42b and the respective portions of the specification. Kuracina et al. discloses a safety needle assembly including a hub (112), a needle cannula (10), a biasing element in the form of a spring (19), and an elongated shield (22) pivotably movable between a first exposed position and a second shielding position. The pivot point of the shield movement can be considered the distal end of the hub (112) from where the shield (22) pivots to the distal end of the needle cannula (10). The shield (22) is maintained in the first position by a latch mechanism, defined as elements (44) and (21), which extends between the shield (22) and the hub (112). Kuracina et al. also discloses a release arrangement that includes a moveable member (26) that engages with the latch mechanism and causes the release of the latch mechanism.

In regards to claim 2, Kuracina et al. discloses a safety needle assembly as recited in claim 1 wherein the moveable member (26) comprises a first finger tab (49)

with a surface adapted for engagement with the latch mechanism. The latch mechanism is released upon movement of the first finger tab (49).

In regards to claim 3,4, and 5, Kuracina et al. discloses a safety needle assembly as recited in claim 2 wherein the latch mechanism comprises an elongate member (21), including a tab on the end surface, that is in frictional engagement with a recess in element (44). The movement of the first finger tab (49) causes the camming surface to cam the tab out of frictional engagement with the recess of element (44).

In regards to claims 7 and 8, Kuracina et al. discloses a safety needle assembly as recited in 1 wherein the shield (22) further comprises structure (41) in the form of a cannula lock to lock the shield (22) in the shielding position. See Figure 42b.

In regards to claim 9, Kuracina et al. discloses a safety needle assembly as recited in claim 1 wherein the assembly further includes a pair of wings (16) extending from opposing lateral sides of said hub.

In regards to claims 10 and 12, Kuracina et al. discloses a safety needle assembly as recited in claim 1 wherein the hub (112) comprises structure (101) and (16) for attaching to another medical device and wherein the hub (112), the shield (22), and the biasing element (19) are integrally formed and the biasing element (19) extends from the distal end of the hub to the proximal end of the shield.

In regards to claim 24, Kuracina et al. discloses a safety needle that includes all of the limitations recited. Kuracina et al. discloses a housing (112), a needle cannula (10), and an elongated shield (22) pivotably connected to the distal end of the housing (112). The shield (22) is biased towards a shielded position by element (19) and is

latched to the housing by elements (21) and (44). The housing (112) includes a squeezable release mechanism (27) wherein squeezing the mechanism (27) causes the shield (22) to be released from the latched position.

Kuracina et al. clearly discloses a method of passively activating a safety needle that includes all of the limitations recited in claim 15. The inherent use of the device disclosed by Kuracina et al. meets the limitations disclosed in claim 15. Kuracina et al. provides a safety needle system comprising a hub (112), a needle cannula (10), a pivotable shield (22), and a biasing element (19). A latch mechanism made up of elements (21) and (44) is also provided for keeping the shield in the exposed position. The latch mechanism is releasable through engagement with a release mechanism (26). The needle is then inserted into a patient and the release mechanism (26) is then grasped to release the latch mechanism and the shield. The shield is then pivoted forward to a protected position.

In regards to claims 16 and17, Kuracina et al. discloses a method as recited in claim 15 wherein the grasping step comprises squeezing the release mechanism. The release mechanism can be squeezed or grasped when using the device and the same result will be achieved. In regards to claim 17, the grasping step occurs upon the withdrawal of the needle to prevent an accidental needle-stick from happening.

In regards to claims 20 and 21, Kuracina et al. discloses a method as recited in claim 15 wherein the latch mechanism comprises an elongate member (21) with a tab at the end surface which frictionally engages with the recess of element (44).

In regards to claim 22, Kuracina et al. discloses a method as recited in claim 21 wherein the release mechanism (26) comprises a first finger tab (49), which causes the tab to move during the grasping step and thereby releases the shield.

Claims 1,2,6-8,10-14, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison (5,584,818).

Morrison clearly discloses a safety needle assembly that includes all of the limitations as recited in claim 1. See Figures 11-13 and the respective portions of the specification. Morrison discloses a safety needle with a hub made up of elements (4) and (5), a needle cannula (2) extending from the distal end of the hub, a biasing element (17) in the form of a leaf spring, and an elongated shield (1) that is pivotably movable between a first position exposing the needle cannula (2) and a second position covering the needle cannula (2). The pivot point of the shield movement can be considered the distal end of the hub from where the shield (1) pivots to the distal end of the needle cannula (2). The shield (1) is maintained in the first position by latch mechanism (9), which extends between the shield (1) and element (26) of the hub. Morrison discloses a release arrangement comprising moveable member (26) that extends from the hub and engages with the latch mechanism (9) and therefore causes release of the shield (1).

In regards to claim 2, Morrison discloses a safety needle assembly as recited in claim 1 wherein the moveable member (26) comprises a first finger tab (27) that includes a camming surface. The movement of the first finger tab (27) releases the latch mechanism (9) and allows the shield to pivot forward.

In regards to claim 6, Morrison discloses a safety needle assembly as recited in claim 2 wherein the assembly further includes a second finger tab (24) in opposing relation to the first finger tab (27). The first finger tab (27) is movable upon application of pressure between the second tab (24) and the first tab (27).

In regards to claim 7 and 8, Morrison discloses a safety needle assembly as recited in claim 1 wherein the shield further includes structure, including a cannula lock (21), for maintaining the shield in the second position.

In regards to claim 10 and 11, Morrison discloses a safety needle assembly as recited in claim 1 wherein the hub comprises structure for attachment to another medical device (3) and wherein the biasing element (17) is a leaf spring.

In regards to claim 12, Morrison discloses a safety needle assembly as recited in claim 1 wherein the biasing element (17), the shield (1), and the hub are integrally formed with the biasing element extending from the distal end of the hub to the proximal end of the shield (1).

In regards to claim 13 and 14, Morrison discloses a safety needle assembly as recited in claim 1 wherein the assembly further comprises removable package covering (14) which covers needle cannula (12) and can prevent the shield from extending to the second position.

In regards to claim 24, Morrison discloses a safety needle assembly that includes all of the limitations recited. Morrison discloses a needle assembly that includes a housing defined as elements (4) and (5), an elongated shield (1) pivotably connected to the distal end of the housing and biased to the shielding position. The shield is latched

to the housing against the bias. The housing also includes a squeezable release mechanism (24) extending in a proximal direction of the assembly. The mechanism (24) can be squeezed and rotated to release the shield (1) from the latched position thereby permitting the bias to move the shield to the shielding position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuracina et al. (6,443,929) in view of Bujan (3,064,648).

Kuracina et al. discloses a method that includes all of the limitations as recited in claim 15. Kuracina et al. teaches to include a pair of wings (16) to the hub (112) wherein the wings (16) do not interfere with the latch mechanism as recited in claim 19. Kuracina et al. does not teach to bend the wings during insertion of the needle.

Bujan discloses a method of inserting a needle assembly. See Figures 1-6 and the respective portions of the specification. Bujan teaches to bend the wings (18) to a dorsal position during the insertion of the needle. This helps to locate the position of the needle tip and makes it easier for the user to grip. See col. 2, lines 37-43.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to operate the wings of the device, as disclosed by Kuracina et al., with the method disclosed by Bujan to make it easier for the technician to guide the device to the correct destination.

Allowable Subject Matter

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5151089 A to Kirk, III et al.
US 5192275 A to Burns
US 5312369 A to Arcusin
US 5348544 A to Sweeney
US 5374255 A to Nathan
US 5599313 A to Gyure et al.
US 5599318 A to Sweeney et al.
US 5672160 A to Osterlind et al.
US 5672161 A to Allen et al.
US 5681295 A to Gyure et al.
US 5693022 A to Haynes
US 5733265 A to Bachman et al.
US 5746726 A to Sweeney et al.
US 5910130 A to Caizza et al.

US 5913846 A to Szabo
US 6280420 B1 to Ferguson et al.
US 6309376 B1 to Alesi
US 6319232 B1 to Kashmer
US 6635032 B2 to Ward, Jr
US 6796968 B2 to Ferguson et al.
US 6837877 B2 to Zurcher
US 6860871 B2 to Kuracina et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS

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